REMARKS

Favorable reconsideration of this application, in light of the preceding amendments and following remarks, is respectfully requested.

Claims 1, 3, 5-7, 9, 14-15, 22, 24 and 25 are pending in this application. Claims 1, 3, 5-7, 9, 14-15, 22, 24 and 25 are amended and claims 2, 4, 8, 10-13, 16-21, 23 and 26-28 have been cancelled. Claim 1 is the independent claim.

Applicants respectfully note that the present action does not indicate that certified copies of all priority documents have been received by the U.S.P.T.O. Applicants respectfully request that the Examiner's next communication include an acknowledgement of receipt of the certified copies of all priority documents.

Applicants also respectfully note that the present action does not indicate that the drawings have been accepted by the Examiner. Applicants respectfully request that the Examiner's next communication include an indication as to the acceptability of the filed drawings or as to any perceived deficiencies so that the Applicants may have a full and fair opportunity to submit appropriate amendments and/or corrections to the drawings.

Information Disclosure Statement

The Examiner states that Applicant's IDSs are acknowledged and considered except for some foreign references without English translations that have been crossed out, and the full context of the cited foreign references couldn't be determined from only the English translations of Abstracts. Applicants respectfully disagree.

MPEP 609.04(a) states a "submission of an English language abstract of a reference may fulfill the requirement for a concise explanation". However, in the interest of advancing prosecution, Applicants are providing English equivalents of 2 of the 3 Japanese publications, which are listed in the enclosed PTO-1449. Applicants respectfully request that the next U.S.P.T.O. communication including an initialed copy of the attached PTO-1449 form indicating that all of the references listed have been considered.

Specification Objections

The specification has been objected to under 35 U.S.C. § 132(a) because it allegedly introduces new matter into the disclosure. Applicants respectfully submit that the 2007 and 2008 Sequence Listings were filed in error. A copy of a Sequence Listing in computer readable form is enclosed on the attached CD. The undersigned states his belief that the information recorded in computer readable form is identical to the written (hard copy) Sequence Listing provided herewith.

Therefore, withdrawal of the objections to the specification is respectfully requested.

Rejections under 35 U.S.C. § 112

Second Paragraph

Claims 2 and 8-9 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the

subject matter which Applicants regard as the invention. Applicants respectfully traverse this rejection for the reasons stated below.

Regarding claim 2, the Examiner alleges that the limitation "cancer specific antibody" is not explicitly defined in either the claims or the specification. Applicants respectfully disagree. Not only is the term "cancer specific antibody" well known to those skilled in the art, the definition of the term "cancer specific antibody" can be explicitly found on page 16, lines 18-20 of the specification, e.g., "a cancer specific antibody that recognizes a surface molecule of a specific cancer cell as an antigen".

Regarding claims 8 and 9, the Examiner states that HBV surface antigen comprises multiple proteins, called L, M or S surface proteins, and HBV surface antigen (HBsAg) refers to S (small) surface antigens, which do not comprise pre-S1 or pre-S2 peptide, in scientific literature. However, claims 8 and 9 appear to refer to the HBV surface antigen having a pre-S region. Applicants have amended claim 9 as suggested by the Examiner and cancelled claim 8.

The Applicants, therefore, respectfully request that the rejection to Claims 2 and 8-9 under 35 U.S.C. § 112, second paragraph, be withdrawn.

First Paragraph

Claims 1-3, 5-9, 14-16, 22, 24 and 25 stand rejected under 35 U.S.C. § 112 as allegedly failing to comply with the written requirement. Applicants respectfully traverse this rejection for the reasons detailed below.

Applicants have amended the claims to recite "substance carrier". The main purpose of the "substance carrier" is to carry the substrate to a target cite (for example, cells and tissues. The Examiner alleges that the Specification does not describe the clinical benefit of the present invention. Applicants respectfully disagree. The Specification describes the experimental system for the treatment of carcinoma of nude rats, which is a model of the treatment of human diseases. The nude rats and nude mice are capable of receiving a transplant of cells derived from a variety of organisms including a human. If a human-derived cell or a cell derived from a human related species is transplanted into a nude rat, the nude rat can be used as the model of the treatment of human diseases, which is well known by those skilled in the art.

Further, the Examiner alleges that "a substance to be transferred into a cell" and "an antibody" are not described in the Specification in such a way as to enable those skilled in the art to make and/or use the invention. Applicants respectfully disagree.

Applicants submit that the Examiner is incorrect in his statement that only a specific substance to be transferred into a cell (HSV1-tk) is usable in the claims. According to Ward et al. (Virus Genes Vol. 23:1, p.97-104, 2001) cited in the Office Action by the Examiner, the substance to be transferred into a cell is expressed in a cell, and then naturally (but not forcibly) encapsulated into a particle. In the case where the substance to be transferred into a cell is encapsulated into a particle with this method, a ratio at which the substance to be transferred into a cell is encapsulated depends on the type of the substance to be transferred into a cell.

However, even with this method, encapsulating various kinds of substances to be transferred into a cell into a particle at a specific rate, albeit slightly, is possible.

The encapsulating method usable in the present set of claims may be selected from a variety of methods and is not limited to a specific method, for example, an electroporation method, ultrasonic method, simple diffusion method, and a method using charged lipids (see for example line 30, page 17 to line 3, page 18 of the English Specification). With these methods, adjusting a ratio at which the substance to be transferred into a cell is encapsulated into a particle may be possible. Applicants submit that these methods are well-known by one skilled in the art, and further, one skilled in the art would understand from the Specification that encapsulating various substances to be transferred into a cell into the hollow nanoparticles is possible.

For further evidence, Applicants attach Declarations A and B executed by Shunichi Kuroda, and submit that any substance to be transferred to a cell can be employed in the present set of claims. The Examiner appears to be mistaken that only a specific antibody can be used in the present set of claims. Employing a variety of antibodies is possible, e.g., to carry the substance to be transferred into a cell to the target cell or to the target tissue. Those skilled in the art would know that antibodies recognize a specific antigen. Therefore, one skilled in the art would understand from the description of the Specification that carrying the substance to be transferred into a cell to the target cell or to the target tissue by selecting an antibody as needed may be possible. (See also Declaration C).

For all of the above reasons, the Applicants, therefore, respectfully request that the rejection to Claims 1-3, 5-9, 14-16, 22, 24 and 25 under 35 U.S.C. § 112 be withdrawn.

Rejections under 35 U.S.C. § 102

O'Riordan

Claims 1, 5-7, 14, 16, 24 and 25 stand rejected under 35 U.S.C. § 102(b) as being anticipated by WO 99/40214 to O'Riordan. Applicants respectfully traverse this rejection for the reasons detailed below.

The Examiner fails to point out (nor can we find) where O'Riordan teaches "encapsulating a substance to be transferred into a cell for treating a disease, the antibody being a cancer specific antibody or anti-virus protein antibody, and the particle-forming protein including a modified hepatitis B virus surface-antigen L-protein" as recited in independent claim 1. O'Riordan teaches a molecule binding to a cell surface molecule rather than encapsulating the cell as in independent claim 1. (See abstract). Therefore, Applicants respectfully submit that O'Riordan cannot anticipate nor render obvious claim 1.

Claims 5-7, 14, 16, 24 and 25, dependent, directly or indirectly, on independent claim 1, are patentable for the reasons stated above with respect to claim 1 as well as for their own merits.

The Applicants, therefore, respectfully request that the rejection to Claims 1, 5-7, 14, 16, 24 and 25 under 35 U.S.C. § 102(b) be withdrawn.

Kuroda

Claims 1, 5-9, 14, 16, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuroda (WO 01/64930). Applicants respectfully traverse this rejection for the reasons detailed below.

The Examiner fails to point out (nor can we find) where Kuroda teaches "encapsulating a substance to be transferred into a cell for treating a disease, the antibody being a cancer specific antibody or anti-virus protein antibody, and the particle-forming protein including a modified hepatitis B virus surface-antigen L-protein" as recited in independent claim 1. Kuroda teaches a biorecognition molecule being introduced thereto rather than encapsulating the cell as in independent claim 1 (see the claims). Therefore, Applicants respectfully submit that Kuroda cannot anticipate nor render obvious claim 1.

Claims 5-9, 14, 16, 24 and 25, dependent, directly or indirectly, on independent claim 1, are patentable for the reasons stated above with respect to claim 1 as well as for their own merits.

The Applicants, therefore, respectfully request that the rejection to Claims 1, 5-9, 14, 16, 24 and 25 under 35 U.S.C. § 102(b) be withdrawn.

Ojala

Claims 1-3, 5-7, 22, 24 and 25 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Biochem Biophys Res Commun. 2001; 284 (3), 777-784 by Ojala et al. (hereinafter "Ojala"). Applicants respectfully traverse this rejection for the reasons detailed below.

The Examiner fails to point out (nor can we find) where Ojala teaches "encapsulating a substance to be transferred into a cell for treating a disease, the antibody being a cancer specific antibody or anti-virus protein antibody, and the particle-forming protein including a modified hepatitis B virus surface-antigen L-protein" as recited in independent claim 1. Ojala teaches a molecule binding to a cell surface molecule rather than encapsulating the cell as in independent claim 1. (See abstract). Therefore, Applicants respectfully submit that Ojala cannot anticipate nor render obvious claim 1.

Claims 2-3, 5-7, 22, 24 and 25, dependent, directly or indirectly, on independent claim 1, are patentable for the reasons stated above with respect to claim 1 as well as for their own merits.

The Applicants, therefore, respectfully request that the rejection to Claims 1-3, 5-7, 22, 24 and 25 under 35 U.S.C. § 102(b) be withdrawn.

Rejections under 35 U.S.C. § 103

O'Riordan in view of Rosenfeld

Claim 15 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over O'Riordan in view of Annals of Surgery 1997, 225()5): 609-618 by Rosenfeld. Applicants respectfully traverse this rejection for the reasons detailed below.

Even assuming *arguendo* that Rosenfeld could be combined with O'Riordan (which Applicants do not admit), the Examiner has failed to show how Rosenfeld remedies the deficiencies of O'Riordan with respect to independent claim 1. Thus,

claim 15 is patentable over O'Riordan and Rosenfeld for the reasons set forth above with respect to independent claim 1.

The Applicants, therefore, respectfully request that the rejection to Claim 15 under 35 U.S.C. § 103(a) be withdrawn.

Double Patenting

Claims 1-3, 5-7, 22, 24 and 25 stand rejected on the grounds of non-statutory obviousness-type double patenting over claims 1-11 of 10/594,612 (hereinafter '612). Claims 1-3, 5-9, 14-16, 22, 24 and 25 stand provisionally rejected on the grounds of non-statutory obviousness-type double patenting over claims 1-3, 6, 8 and 9 of co-pending application number 11/987,476 (hereinafter '476). Applicants respectfully traverse this rejection for the reasons detailed below.

Applicants cannot remedy this rejection at this time and request that this rejection be held in abeyance. This is because none of the co-pending applications has matured into a patent. Should all outstanding issues in the present application be resolved save for the double-patenting rejection, and should none of the co-pending applications have by such time matured into a patent, then the Examiner should allow the instant application and thus any double patenting rejection should attach to the above-noted co-pending applications.

The Applicants, therefore, respectfully request that the rejection of the claims on the grounds of non-statutory obviousness-type double patenting be withdrawn.

CONCLUSION

In view of the above remarks and amendments, the Applicants respectfully submit that each of the pending objections and rejections has been addressed and overcome, placing the present application in condition for allowance. A notice to that effect is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to contact the undersigned.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Erin G. Hoffman, Reg. No. 57,752, at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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Enclosures: PTO-1449
Declarations A, B and C
Replacement Sequence Listing